REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 1-5, 7-11, and 13-19 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Applicants regret the confusion regarding the numbering of the claims. Former claims 16-19 are now shown as being renumbered, consistent with the examiner's indication, as claims 14-17 with the claim dependencies also corresponding renumbered.

Claims 1, 4, 5, 7-11 and 13-17 have been rejected under 35 U.S.C. §112, first paragraph, because the examiner states that the specification, while being enabling for monoclonal antibodies having accession numbers I-2134, I-2135, I-2136, I-2137 and I-2138, does not reasonably provide enablement for any other monoclonal antibody capable of binding Placental Protein 13 (PP-13). The examiner asserts that the specification fails to disclose how to make and use any other monoclonal antibodies that can bind PP-13 with high affinity nor does it disclose any other monoclonal antibodies with binding characteristics as claimed in claims 4 and 14. This rejection is respectfully traversed.

Claim 1 has been amended to more specifically define the claimed monoclonal antibodies (mAb) where the sensitivity of

PP-13 binding has been defined as being at 10 pg/ml in a sandwich ELISA assay. Support for this recitation is found on page 12, lines 24-28, page 13, lines 4-12, Fig. 12 and Fig. 13. The presently claimed mAb is also defined as being of the IgG type. Support for this recitation is found on page 8, line 21, and in Fig. 13.

Regarding the guidance provided by the specification, the specification discloses in great detail how to obtain mAb according to the invention, and provides specific examples of such antibodies. The steps for obtaining the claimed mAb as disclosed in the specification include the following:

a. PP-13 is isolated and purified from human placenta (page 5, line 28);

b. Animals such as mice are injected with the purified PP-13 (page 7, lines 24-28);

c. The animals are boosted with PP013 to obtain predominantly IgG antibodies (secondary immune response) (page 8, lines 2-4);

d. The animals are sacrificed and antibody-producing cells obtained from the spleens are fused with myeloma cells to produce hybridoma clones (page 8, lines 4-8);

e. The hybridoma clones are screened for specific mAb producers by a capture ELISA (page 8, line 27 to page 9, line 19, and Fig. 2);

f. The clones identified in step (e) were further screened by a sandwich ELISA (page 9, lines 9-19, and Fig. 4);

g. Clones which gave a good response were screened in an additional sandwich ELISA (page 9, lines 21-29 and Fig. 5).

Accordingly, the specification discloses to one of skilled in the art how to make a monoclonal IgG antibody capable of binding PP-13 and of detecting PP-13 at a concentration of 10 pg/ml in a sandwich ELISA assay.

The present specification is enabled for making and using a generic monoclonal IgG antibody as presently claimed. This is evidenced by the mAbs produced by hybridomas I-2134, I-2135, I-2136, I-2137, and I-2138, which were obtained by following the guidance provided by the present specification. Accordingly, one of skill in the art would instantly recognize that the specification is enabled for obtaining other mAbs similar to the above mentioned six mAbs, which further establishes that a representative sampling of mAbs can be obtained without undue experimentation. Therefore, the rejected

claims are fully enabled to those of skill in the art from a reading of the specification.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 2 and 3 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is obviated by the executed declaration of biological material deposit attached hereto.

Claims 1-5, 7-11 and 13-17 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is respectfully traversed.

Support for the amendment to claim 13 is found on page 9, line 22 to page 10, line 14.

Regarding claim 4, applicants believe that one of skill in the art would be clear about what conditions are considered conducive to the production of a signal generated by a signal-generating molecule. The remaining indefiniteness issues are obviated by the amendments to the claims.

Claims 1, 4-5, 7, 9-11, 14, 15, and 17 have been rejected under 35 U.S.C. §102(b) as being anticipated by Admon et al. (WO 99/38970). This rejection is respectfully traversed.

WO 99/38970 has a publication date of August 5, 1999. However, the instant applicant claims the benefit of priority from Israeli application 129273, filed March 30, 1999, as noted on the application data sheet and on the executed declarations. The March 30, 1999, filing date of Israeli application 129273 antedates the August 5, 1999, publication date of WO 99/38070. Accordingly, WO 99/38970 is not available as a prior art reference. A courtesy copy of Israeli application 129273 filed March 30, 1999 is attached hereto for the examiner's convenience.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 8 and 16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Admon in view of Silberman (U.S. Patent 5,198,366). This rejection is respectfully traversed.

For the reasons discussed above in the anticipation rejection over Admon, the applied Admon reference is not available as prior art against the present claims. Silberman alone cannot lead one of ordinary skill in the art to the present invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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